

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/
FENFLURAMINE/DEXFENFLURAMINE)
PRODUCTS LIABILITY LITIGATION

MDL NO. 1203

THIS DOCUMENT RELATES TO:

SHEILA BROWN, et al.

v.

CIVIL ACTION NO. 99-20593

AMERICAN HOME PRODUCTS
CORPORATION

2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

9100

Bartle, J.

June 27, 2013

Judy K. Bell ("Ms. Bell" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Glendon Bell, Ms. Bell's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or
(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In August, 2007, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Duncan Salmon, M.D. Based on an echocardiogram dated April 20, 2007, Dr. Salmon attested in Part II of claimant's Green Form that Ms. Bell suffered from moderate mitral regurgitation, mitral

3. (...continued)
contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

annular calcification,⁴ and an abnormal left atrial dimension.⁵ Based on such findings, claimant would be entitled to Matrix B-1, Level II benefits in the amount of \$101,215.⁶

In the report of claimant's echocardiogram, the reviewing cardiologist, Nirmal Shah, M.D., stated that claimant had "[m]ild [l]eft [a]trial [e]nlargement."⁷ The Settlement Agreement defines an abnormal left atrial dimension as a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view or a left atrial antero-posterior systolic dimension greater than 4.0 cm in the parasternal long axis view. See Settlement Agreement § IV.B.2.c.(2)(b)ii).

In November, 2007, the Trust forwarded the claim for review by Siu-Sun Yao, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Yao determined that there was no

4. The presence of mitral annular calcification requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)ii)d).

5. In addition, Dr. Salmon attested that claimant suffered from aortic stenosis and New York Heart Association Functional Class I symptoms. These conditions are not at issue in this claim.

6. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). Although the Trust disputes that claimant had moderate mitral regurgitation, we need not resolve this issue given our disposition with respect to claimant's left atrial dimension, which is one of the complicating factors needed to qualify for a Level II claim.

7. Although the report of claimant's echocardiogram appears to contain measurements of Ms. Bell's left atrial dimension, those measurements are not legible on the copy in the record.

reasonable medical basis for Dr. Salmon's representation that Ms. Bell had an abnormal left atrial dimension. Specifically, Dr. Yao determined claimant had a left atrial supero-inferior systolic dimension of 4.8 cm in the apical four chamber view and a left atrial antero-posterior systolic dimension of 3.3 cm in the parasternal long axis view.

Based on the auditing cardiologist's findings, the Trust issued a post-audit determination denying the claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁸ In contest, Ms. Bell argued that there was a reasonable medical basis for Dr. Salmon's representation of an enlarged left atrial dimension. In support, she submitted a videotaped statement of Dr. Salmon under oath, wherein he explained how he concluded that claimant had an abnormal left atrial dimension. In addition, claimant submitted a number of still-frame images taken from claimant's April 20, 2007 echocardiogram, which purportedly demonstrated an abnormal left atrial dimension. Claimant also contended that the "minute fractional differences in interpretation can lead to varying numbers" and that the auditing cardiologist simply substituted his opinion for that of the

8. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Bell's claim.

attesting physician. Claimant further suggested that despite the auditing cardiologist's "difference of opinion" there was a reasonable medical basis for Dr. Salmon's finding of an abnormal left atrial dimension and that if the "Attesting Cardiologist has a rational basis for his opinions" we "should find [the] same."⁹

Although not required to do so, the Trust forwarded the claim to the auditing cardiologist for a second review. Dr. Yao submitted a declaration in which he again concluded that there was no reasonable medical basis for the attesting physician's finding that Ms. Bell had an abnormal left atrial dimension. Specifically, Dr. Yao stated:

At audit, I found left atrial dimensions of 33mm in the parasternal long-axis view and 48mm in the apical 4-chamber view, and found that the left atrium was not enlarged. At Contest, I again reviewed the April 20, 2007 echocardiogram, including those points indicated by Dr. Salmon, and again found that Claimant's left atrial dimensions are not enlarged. The left atrial dimension should be measured at end-systole, and the supero-inferior systolic dimension should be measured from the mitral annular plane to the inside edge of the [left atrium] wall (the pulmonary veins and mitral valve leaflet tips should be excluded). When properly measured, Claimant's left atrium is not enlarged, and I affirm my findings at audit that there is no

9. Claimant also argued that, in reviewing her claim, we should consider "deficiencies in the audit program," that certain claims have passed audit "mistakenly," and that certain auditors have been removed for undisclosed conflicts. We disagree. Claimant does not attempt to explain how these circumstances had any impact on Dr. Yao's review of her specific claim. As we consistently have stated, the relevant inquiry is whether a claimant has established a reasonable medical basis for his or her claim, an inquiry that is to be made on a claim-by-claim basis. See, e.g., PTO No. 6280 at 9 (May 19, 2006).

reasonable medical basis for the Attesting Physician's representation to the contrary.

The Trust then issued a final post-audit determination again denying the claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807; Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why the claim should be paid. On August 21, 2008, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 7925 (Aug. 21, 2008).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant did not submit a response to the Trust's statement of the case and thus relied only on the material submitted during the contest phase of the audit process. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor¹⁰ to review claims after the Trust and claimant have had their opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a

10. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. at Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's finding that she had an abnormal left atrial dimension. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded there was no reasonable basis for the attesting physician's finding that claimant had an abnormal left atrial dimension. Specifically, Dr. Vigilante explained:

Visually, the left atrium appeared normal in size. I digitized the cardiac cycles in the parasternal long-axis and apical four chamber views in which the left atrium appeared the largest. I measured the left atrium by electronic calipers. I determined that the left atrial antero-posterior diameter was

3.3 cm. This measurement was taken between the posterior root of the aorta and posterior left atrial wall at the level of the aortic valve. This line was perpendicular to the supero-inferior axis of the left atrium. I determined that the left atrium measured 4.9 cm in the supero-inferior dimension. This measurement was taken from the mitral annulus to the posterior left atrial wall. This measurement was perpendicular to the mitral annulus. I excluded pulmonary vein structures in this measurement. My left atrial dimension measurements correspond well with an LAA measurement of 18.1 cm² noted in the apical four chamber view. There were no sonographer-determined left atrial dimension measurements in the apical four chamber view. I paid close attention to Dr. Salmon's documented time in his sworn testimony. However, the left atrium measured no more than 4.9 cm in the supero-inferior dimension in these frames.¹¹

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. As an initial matter, claimant does not adequately refute the findings of the auditing cardiologist or the Technical Advisor. In particular, Dr. Yao determined Ms. Bell's left atrial supero-inferior systolic dimension was 4.8 cm in the apical four chamber view and her left atrial antero-posterior systolic dimension was 3.3 cm in the parasternal long axis view. Although claimant provided still-frame images that purportedly demonstrated an abnormal left atrial dimension, Dr. Yao reviewed these still-frame images and determined that claimant's left atrial dimension was not properly measured. Specifically, Dr. Yao observed, "The left atrial

11. Dr. Vigilante also determined that there was a reasonable medical basis for Dr. Salmon's representation that claimant's echocardiogram demonstrated moderate mitral regurgitation.

dimension should be measured at end-systole, and the supero-inferior systolic dimension should be measured from the mitral annular plane to the inside edge of the [left atrial] wall (the pulmonary veins and mitral valve leaflet tips should be excluded)."¹² Claimant did not respond to these specific determinations.

Similarly, Dr. Vigilante measured Ms. Bell's left atrial supero-inferior systolic dimension to be 4.9 cm in the apical four chamber view and her left atrial antero-posterior systolic dimension to be 3.3 cm in the parasternal long axis view. Dr. Vigilante also "paid close attention to Dr. Salmon's documented time" in the still-frame images and concluded the left atrium measured no more than 4.9 cm in those frames.¹³ Mere disagreement with the auditing cardiologist and the Technical Advisor without identifying specific errors by them is insufficient to meet a claimant's burden of proof.

Moreover, to the extent claimant argues that inter-reader variability accounts for the differences in the opinions of the attesting physician and the auditing cardiologist, such argument is misplaced. The concept of

12. For this reason as well, we disagree with claimant that the auditing cardiologist simply substituted his opinion for that of the attesting physician or that it was merely a "difference of opinion." Instead, Dr. Yao specifically found that there was no reasonable medical basis for the attesting physician's finding of an abnormal left atrial dimension.

13. Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.

inter-reader variability is already encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. In this instance, the opinions of claimant's cardiologist cannot be medically reasonable where the auditing cardiologist and Technical Advisor concluded, and claimant did not adequately dispute, that Ms. Bell's left atrial dimension was not enlarged. To conclude otherwise would allow a claimant with a left atrial dimension of less than 5.3 cm in the apical four chamber view or 4.0 cm in the parasternal long axis view to receive Matrix Benefits. This result would render meaningless the standards established in the Settlement Agreement.¹⁴

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had an abnormal left atrial dimension. Therefore, we will affirm the Trust's denial of Ms. Bell's claim for Matrix Benefits and the related derivative claim submitted by her spouse.

14. Moreover, the Technical Advisor took into account the concept of inter-reader variability as reflected in his statement, "An echocardiographer could not reasonably conclude that left atrial enlargement was present on this study when the left atrium was measured in appropriate views by quantitative methods even taking into account inter-reader variability."